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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

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EXAMINER
MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,610	DENYER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7-9,12,13,15-21 and 39-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *1,3,7-9,12,13,15-20 and 39-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/1/2005 have been fully considered but they are not persuasive.

2. As to claim 1, the drug delivery device is not positively claimed. What is positively claimed is a plurality of containers, each container containing a drug; and an electronic data carrier removable from the plurality of container, the carrier including a read/write memory for storing drug treatment information. The limitation of "for use by the drug delivery device" is functional language. The plurality of containers was rejected under 103(a) duplication of parts. Wolf et al. meets the limitation of an electronic data carrier removable from the plurality of container, the carrier including a read/write memory for storing drug treatment information. The memory is used by a drug delivery device for indicating remaining doses.

3. As to claim 19, the drug delivery device is not positively claimed. What is positively claimed is a memory located within an electronic data carrier; and an output. The applicant argues there is not an output for transmitting information to the drug delivery apparatus. The claim is not specific as to what type of treatment information. As shown in figure 10 the electronic data carrier can be connected to part 790 which is part of the drug delivery device of Wolf et al. Wire 1040 is connected to the electronic data carrier and transmits information (dosage) to part 790. Wire 1040 would inherently be connected to an output in order to be able to send information via 1040 to part 790 of the drug delivery device.

4. As to claim 20, the applicant has added the limitation "a read/write memory for storing the drug treatment information for use by the drug delivery device. The applicant admits that the data carrier of Anderson et al. can be removed and reprogrammed (written). The device of Anderson et al. is able to read the written information on the data carrier. The claim is silent as to where and how the memory is written. Therefore, the data carrier of is anticipated by Anderson et al. The Applicant argues that the data carrier is completely incapable of being written to by a drug delivery device, however the claim does not include a limitation that the drug delivery device is configured to write on to the data carrier. Because the data carrier can be reprogrammed/rewritten outside of the device and also read by the device, the disclosure of Anderson et al. reads on the limitation of read/write.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 42, 43, 45, 46, 49, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 42, 43, 45, 46, 49, and 50 the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the drug package alone or the combination of the drug package and the drug delivery device. The Applicant sets forth the combination of the package and the device when describing the what the device is (a nebulizer), which is inconsistent with preamble and body of claims 39, 40, and 47, that sets forth the

subcombination of drug package (the bodies of the claims do not positively claim the drug delivery device). Applicant is required to make the language of the claims consistent with the intent of the claims.

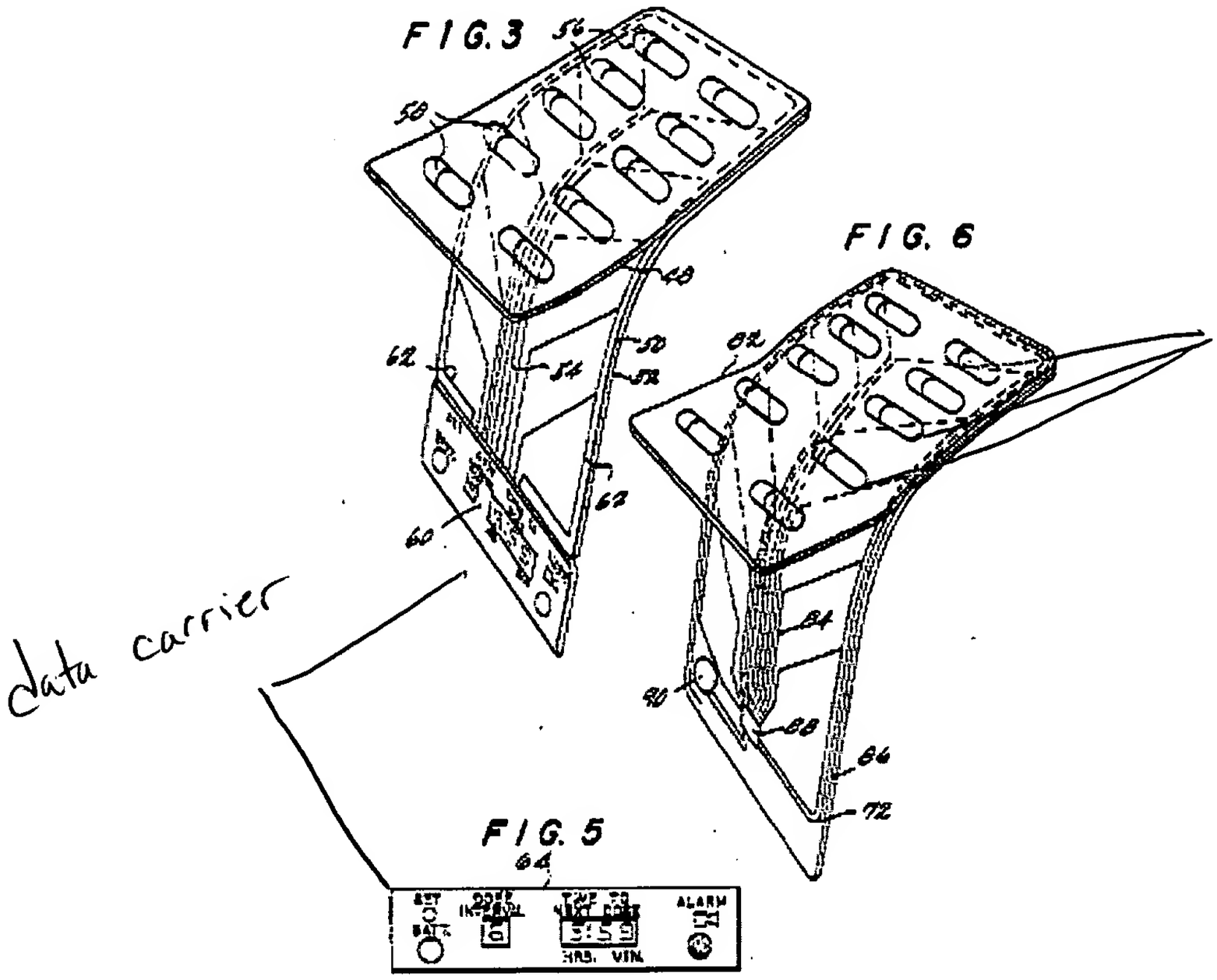
Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 39, 40, 41, 44, 48, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon 4617557.

9. Gordon teaches a plurality of drug container, each container containing a drug; and an electronic data carrier separate from the drug container, the carrier including drug treatment information, wherein the date carrier is a radio frequency device (col. 6, lines 47-58); and wherein the drug treatment information includes at least one of the following items: an identity of the drug which is to be delivered; a security code; a desired dose amount; *a desired frequency of treatment* (col. 4, line 22-33) or an expiration date of the drug.



10. Claims 13, 17, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. 5237987.

11. As to claims 13, 17, and 18, Anderson et al. teaches a drug delivery device comprising: a delivery portion 52; an electronic input arranged remotely from the delivery portion (col. 13, lines 1-3); a removable electronic data carrier (see claim 5); a delivery controller 28 for controlling the amount of the drug delivered to the patient based on received treatment information; an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery (col. 13, lines 13-18); and wherein the drug delivery device is selected from one

of a *pneumatic nebulizer* (col. 9, lines 3-27); a piezo-electric nebulizer, or an ultrasonic nebulizer.

12. As to claim 20, Anderson et al. teaches a drug delivery system comprising: a drug delivery apparatus, the apparatus having a medication chamber 48; and electronic input 28 arranged remotely from the medication chamber; an electronic data carrier removable from the drug delivery device containing treatment information and including an output for transmitting treatment information (see claim 5).

13. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell et al. 5590648.

14. Mitchell et al. teaches drug delivery device comprising: a delivery portion (col. 4, lines 39-45); an electronic input arranged remotely from the delivery portion 68; a removable electronic data carrier (col. 7, lines 57-64); a delivery controller 12 for controlling the amount of the drug delivered to the patient based on received treatment information; and an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery (col. 5, lines 8-14).

15. Claims 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. 5505195.

16. Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus removable from the drug delivery device, comprising a memory located within the electronic data carrier for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 41-58).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1-4, 7, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al.

19. Wolf et al. teaches a drug package comprising: a container 140 containing drugs; an electronic data carrier 110 removable from the container; wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of the drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the drug which is to be delivered; the number of treatments available from the drug package; wherein the data carrier is arranged to supply drug treatment information to a drug delivery device a number of times corresponding to the number of treatments available (fig. 10, 1035); and wherein the data carrier includes a memory. It should be noted that Wolf et al. fails to teach a plurality of containers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a plurality of containers, since it has been held that mere duplication of the parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

20. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. in view of Castellano et al. 5593390

21. Mitchell et al. teaches the drug delivery device according to claim 13. It should be noted that Mitchell et al. fails to teach wherein the input is a radio frequency input and is arranged to receive and transmit treatment information. Mitchell et al. teached that the recording media (data carrier) is not limited to disclosed types specified in the detailed description (col. 7, lines 62-64).

22. Castellano et al. teaches a device that transfers data using radio frequency. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use radio frequencies of Castellano as an alternative to the data transfer devices taught by Mitchell as an alternate means for transferring data (col. 9, lines 23-26).

Allowable Subject Matter

23. Claim 21 is allowable over the prior art of record.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER